

Exhibit C

MERSILENE*
POLYESTER FIBER MESH
Nonabsorbable Synthetic Surgical Mesh
STERILE

DESCRIPTION

MERSILENE* Polyester Fiber Mesh is constructed from polyethylene terephthalate, the same material used to make MERSILENE* Polyester Fiber Suture, Nonabsorbable Surgical Suture, U.S.P. (ETHICON, LLC.). MERSILENE Polyester Fiber Mesh affords excellent strength, durability and surgical adaptability, along with maximal porosity for necessary tissue ingrowth. The mesh is approximately 0.010 inches thick and is a highly flexible and compliant material.

MERSILENE mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The fiber junctions are not subject to the same work fatigue exhibited by more rigid metallic meshes. This bi-directional elastic property allows adaption to various stresses encountered in the body.

ACTIONS

MERSILENE mesh is a nonabsorbable mesh used to span and reinforce traumatic or surgical wounds to provide extended support during and following wound healing. Animal studies show that implantation of MERSILENE mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes.

INDICATIONS

This mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

CONTRAINDICATIONS

When this mesh is used in infants or children with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows.

MERSILENE polyester fiber mesh in contaminated wounds should be used with the understanding that subsequent infection may require removal of the material.

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WARNINGS

MERSILENE mesh is provided by ETHICON, LLC. as a sterile product. Unused MERSILENE Mesh which has been removed from the package may be resterilized not more than one time by a conventional steam autoclaving process at conditions of 250°F (121°C) for 20 minutes. MERSILENE mesh may be also be flash autoclaved not more than one time at conditions of 270°F (132°C) for 10 minutes. Resterilization under any other conditions or by any other means is neither recommended nor endorsed by ETHICON, LLC.

If this product should become stained with blood or soiled, it should not be resterilized for reuse.

PRECAUTIONS

A minimum of 6.5mm (1/4 inch) of mesh should extend beyond the suture line.

ADVERSE REACTIONS

No significant adverse clinical reactions to MERSILENE mesh have been reported. The use of nonabsorbable MERSILENE mesh in a wound that is contaminated or infected could lead to fistula formation and/or extrusion of the mesh.

INDICATIONS FOR USE

It is recommended that nonabsorbable sutures be placed 6.5 to 12.5mm (1/4 to 1/2 inch) apart at a distance approximately 6.5mm (1/4 inch) from the edge of the mesh. Some surgeons prefer to suture an uncut section of mesh that is considerably larger than the defect into position over the wound. The opposite sides are then sutured to assure proper closure under correct tension. When the margin sutures have all been placed, the extra mesh is trimmed away.

HOW SUPPLIED

MERSILENE mesh is available in single packets as sterile, undyed (white) sheets in two sizes. The sizes available are 6 x 11cm (2.5 x 4.5 inches) and 30 x 30cm (12 x 12 inches). Each sheet is 0.25mm (0.010 inch) thick.

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